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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,831	09/24/2003	Gerald F. Sigler	RDID 01034CIP US	6994

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,831	SIGLER ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 (at least part of each), drawn to activated ritonavir derivatives, classified in class 548, subclass 204.

II. Claims 1-10, 13, 14, 23-25 and 27 (at least part of each), drawn to activated saquinavir derivatives, classified in class 546, subclass 152.

III. Claims 1-10, 15 and 16 (at least part of each), drawn to activated amprenavir derivatives, classified in class 549, subclass 449.

IV. Claims 1-10, 17 and 18, (at least part of each), drawn to activated indinavir derivatives, classified in class 544, subclass 360.

V. Claims 1-10, 19, 20, 26 and 28 (at least part of each), drawn to activated nelfinavir derivatives, classified in class 546, subclass 147.

VI. Claims 1-10, 21 and 22 (at least part of each), drawn to activated lopinavir derivatives, classified in class 544, subclass 312.

VII. Claims 1 and 3-10 (at least part of each), drawn to atazanavir derivatives, classified in class 546, subclass 335.

IA. Claims 29-37, 48-50 and 52-54 (at least part of each), drawn to ritonavir immunogens and tracers and antibodies prepared from the immunogens; class 530, subclass 404.

IIA. Claims 29-35, 38, 39, 48-50, 52, 53 and 55 (at least part of each), drawn to saquinavir immunogens and tracers and antibodies prepared from the immunogens; class 436, subclass 546.

IIIA. Claims 29-35, 40, 41, 48-50, 52, 53 and 56 (at least part of each), drawn to activated amprenavir immunogens and tracers and antibodies prepared from the immunogens; class 530, subclasses 405 and 388.9.

IVA. Claims 29-35, 42, 43, 48-53 and 57 (at least part of each), drawn to indinavir immunogens and tracers; class 436, subclass 529.

VA. Claims 29-35, 44, 45, 48-50, 52, 53 and 58 (at least part of each), drawn to nelfinavir immunogens and tracers; class 530, subclasses 405 and 389.8.

VIA. Claims 29-35, 46-50, 52, 53 and 59 (at least part of each), drawn to lopinavir immunogens and tracers; class 436, subclass 544.

VIIA. Claims 29, 31-35, 48-50, 52 and 53 (at least part of each), drawn to atazanavir immunogens and tracers; class 530, subclass 406.

VIII. Claim 60, drawn to an antibody specific for saquinavir having additional specific cross-reactivity requirements.

XI. Claim 61, drawn to an antibody specific for nelfinavir having additional specific cross-reactivity requirements.

X. Claim 62, drawn to an antibody specific for indinavir having additional specific cross-reactivity requirements.

XI. Claim 63, drawn to murine hybridoma SAQ 10.2.1.

XII. Claim 64, drawn to murine hybridoma SAQ 14.1.1.

XIII. Claim 65, drawn to murine hybridoma NEL 5.4.1.

XIV. Claim 66, drawn to murine hybridoma <INDIN>N01.003.12.

XV. Claim 67, drawn to murine hybridoma >INDIN>M-1.158.8.

2) The inventions are distinct, each from the other because of the following reasons:

a) Each of Inventions I and IA, II and IIA, III and IIIA, IV and IVA etc. is related as mutually exclusive species in an intermediate-final product relationship (i.e. activated hapten intermediate and tracer or immunogen final product). Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a reactant useful in making a pro-drug having the same or similar utility to the original drug and the inventions are deemed

patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

b) Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the chemically diverse structures of the different inventions do not have any significant structural feature in common. For example, the saquinavir structure contains both a quinoline and an isoquinoline structure; atazanvir contains a pyridine structure; lopinavir contains a 1,3-diazine structure; ritonavir contains a diazole structure; indinavir contains a pyridine structure as well as a 1,4-piperazine structure. The compounds of each invention are separately searchable in both the patent and technical literature (requiring different structure searches).

It is additionally noted that there is no language in the claims which would require that the linker-functional group be attached to the protease inhibitor radicals at the hydroxy group of the common $-CH_2$-C(OH)-CH-N- moiety as shown in Figures 1-6 and 23.

c) The antibodies of each of Inventions IA, IIA, IIIA, IVA, VA, VIA, VIIA and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of the different inventions have different functions and effects based on the recited diverse characteristics including different requirements for use of specific immunogens for the preparation of the antibodies (e.g.

Invention IA versus IIA), different specificities (e.g. Invention IVA versus IIIA) and/or different cross-reactivity requirements (e.g. Invention X versus Invention VIII).

d) Inventions XI-XV are unrelated to each other as well as being unrelated to all other inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the hybridomas of each of XI-XV is a distinct cell line which produces a single monoclonal antibody having unique specificity and cross-reactivity characteristics. Additionally, the cell lines of the hybridomas are chemically and structurally unrelated to the compounds (activated haptens, tracers and immunogens) and antibodies (specific binding proteins) of the other inventions.

3) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4) Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached on 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 29, 2005

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641